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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,518	03/26/2004	Thomas H. Barrows	ARI 9012	1213
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WARE, DEBORAH K				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,518

Applicant(s)

BARROWS ET AL.

Examiner

DEBBIE K. WARE

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-40 and 43-55 is/are pending in the application.
- 4a) Of the above claim(s) 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-40, 43-48 and 51-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 32-40 and 43-55 are pending in the instant case.

Election/Restrictions

Claims 49-50 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 19, 2006.

Response to Amendment

The amendment filed November 5, 2008, has been received and entered. The amendment has been found persuasive in part except for the following.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-40, 43-48 and 51-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 11/603,818. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims is the scope of the claimed subject matter, wherein the instant claims do not have a protectant and as part of the graft and the lumen of the bioabsorbable filament is centrally placed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The claims are drawn to a graft comprising a bioabsorbable filament and cells comprising epidermal and dermal cells disposed within a lumen of the filament.

The copending claims are drawn to a graft comprising epidermal cells and dermal cells and a bioabsorbable filament having an inner lumen and a protectant.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for the instantly claimed graft because one of ordinary skill in the art would have been motivated by the copending claimed hair graft since the gelatin of the copending claims which serves as a protectant is bioabsorbable and hence the instantly claimed graft would have been expected to provide a hair graft

much like the copending claimed hair graft. Hence, the only difference between the instant claims and the copending claims is scope and one of ordinary skill would have well within their level of skill the selection of a protectant which reads on a bioabsorbable material useful within the inner lumen of the filament as claimed herein.

Therefore, each of the instantly claimed features are recited and taught in the copending claims or are at least suggested by them. Thus, in the absence of persuasive evidence to the contrary the claims are clearly prima facie obvious over the copending claimed subject matter.

Claims 32-40, 43-48 and 51-55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/562,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims is the scope of the claimed subject matter, wherein the instant claims do not specify progenitor cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are discussed above.

The copending claims are drawn to a hair graft comprising a tissue engineered skin having a tissue engineered epidermal layer, a tissue engineered dermal layer and hair follicle progenitor cells and scaffold, therefore.

The instant claims differ from the copending claims in that progenitor cells are not specifically recited in the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a graft as instantly claimed based upon the recited teachings of the copending claims of a tissue engineered skin having a tissue engineered epidermal layer, a tissue engineered dermal layer and hair follicle progenitor cells and scaffold, therefore, because a graft as instantly claimed comprises a filament and broadly defined epidermal and dermal cells disposed therein of which clearly reads on the copending hair graft. The copending hair graft teaches a scaffold which can be made up of a bioabsorbable filament as instantly claimed. The teaching of copending claims recite that the progenitor cells are comprised of dermal cells as instantly claimed herein. Clearly the claimed subject matter is at least suggested by the copending claims and one of skill would have been motivated to provide for a graft as instantly claimed. Each of the instantly claimed features are taught or suggested by the copending claims. Therefore, the claims are rendered prima facie obvious over these copending claims as well.

Claims 32-33, 43-44, 45 and 48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 7, 11, 12, and 13 of copending Application No. 11/107230. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims is the scope of the claimed subject matter, wherein the instant claims do not specify a means per se, however they do not exclude a means wherein a graft can include a filamentary means.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are discussed above.

The copending claims are drawn to a filamentary means which comprises a filament comprising a solid core and a porous sheath that is bioabsorbable and coats at least a portion of the solid core, and cells from hair follicles and cell attachment molecules or cell binding site molecules.

The instant claims differ from the copending claims in that a filamentary means is not specifically recited in the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a graft as instantly claimed based upon the recited teachings of the copending claims of a filamentary means, because a graft as instantly claimed comprises a filament and broadly defined epidermal and dermal cells disposed therein of which clearly reads on the copending agent which is further comprised by a filamentary means of the copending claims. The copending filamentary means teaches the living cells are from hair follicles of which the instant claims are also derived from these hair follicles. Furthermore, the filamentary means can be made up of a bioabsorbable filament as instantly claimed. Clearly the claimed subject matter is at least suggested by the copending claims and one of skill would have been motivated to provide for a graft as instantly claimed. Each of the instantly claimed features are taught or suggested by the copending claims. Therefore, the claims are rendered prima facie obvious over these copending claims as well.

Response to Arguments

Applicant's arguments filed November 5, 2008, have been fully considered but they are not persuasive. The argument that none of the claims disclose or suggest a filament having an exterior surface and lumen having a hydrophilic interior to wick the cells into the lumen is noted. However, the copending claims are broad enough that they do not exclude a lumen having a hydrophilic material as its interior and they do clearly read on and hence teach an interior lumen which is capable of attaching cells thereto. Furthermore, an exterior surface of the filament is an intrinsic feature of the filaments taught in the copending claims. Therefore, the claims remain *prima facie* obvious over these copending claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DKW/
Deborah K. Ware
Examiner
Art Unit 1651

/David M. Naff/
Primary Examiner, Art Unit 1657